

Fleqsuvy (baclofen oral suspension)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Multiple Sclerosis (MS) is an autoimmune disease characterized by the immune system attacking the body's own tissues, leading to the destruction of the protective myelin coating on nerve fibers in the brain and spinal cord. This damage disrupts the transmission of messages between the brain and the rest of the body, causing communication problems and potential disability.

Fleqsuvy (baclofen oral suspension) is a skeletal muscle relaxant that is specifically indicated for the treatment of spasticity resulting from multiple sclerosis. It can also provide benefit to individuals with other spinal cord injuries and/or diseases. Fleqsuvy is available as a 5mg/ml suspension, offering a more potent liquid formulation for convenient administration.

Definitions

"Multiple Sclerosis (MS)" is an autoimmune disease in which the body's immune system mistakenly attacks the protective covering of nerve fibers (myelin) in the central nervous system, leading to communication problems between the brain and the rest of the body.

“**Autoimmune Disease**” is a condition in which the body's immune system mistakenly targets and attacks its own healthy cells and tissues.

“**Central Nervous System (CNS)**” is the part of the nervous system that includes the brain and spinal cord, responsible for receiving, processing, and transmitting information throughout the body.

“**Immune System**” is the body's defense system that protects against infections and diseases by recognizing and attacking foreign substances, such as viruses, bacteria, or abnormal cells.

“**Myelin**” is a fatty substance that forms a protective sheath around nerve fibers, enabling efficient transmission of electrical signals between nerve cells.

“**Spasticity**” is a condition characterized by increased muscle tone and stiffness, leading to involuntary muscle contractions, muscle spasms, and difficulty with movement and coordination.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Fleqsuvy (baclofen oral suspension)** medically necessary when **ALL** of the following criteria are met:

1. The member has **ONE** of the following diagnoses:
 - a. Multiple sclerosis; **or**
 - b. Spinal cord injury or disease; **AND**
2. The member is unable to use, or has tried and failed **BOTH** of the following:
 - a. baclofen oral tablets; **and**
 - b. tizanidine; **AND**
3. Fleqsuvy (baclofen oral suspension) will be prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature; **AND**
4. Chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Fleqsuvy (baclofen oral suspension) will be approved for 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **BOTH** of the following are met:

1. The member still meets the initial criteria.

2. Chart documentation shows the member has experienced a clinical improvement in symptoms since starting the requested medication.

Examples of clinical improvement:

- a. *Reduction in muscle spasms or spasticity.*
- b. *Decreased pain associated with spasticity.*
- c. *Improvement in range of motion or functional abilities.*
- d. *Enhanced ability to perform activities of daily living.*
- e. *Decreased frequency or severity of flexor spasms, clonus, or muscular rigidity.*
- f. *Improvement in overall quality of life related to spasticity symptoms.*

Experimental or Investigational / Not Medically Necessary

Fleqsuvy (baclofen oral suspension) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Alcohol Dependency
- Alcohol Drinking Related Problems
- Alcohol Use Disorders (AUD)
- Alcohol Withdrawal Syndrome
- Anxiety Disorders
- Hiccups
- Lower Urinary Tract Symptoms (LUTS)
- Muscle Cramps
- Muscle Hypertonia
- Nicotine Dependence
- Nicotine Use Disorder
- Opiate Addiction
- Overactive Bladder Syndrome (OABS)
- Recurrent Crying Spells
- Rumination Disorders

Appendix

Table 1: Dosage and Retreatment Information

Indication	Initial Dose	Subsequent Dose	Considerations
Multiple sclerosis	1 mL (5 mg) three times a day for three days	Increase gradually to maximum: 4 mL (20 mg) four times a day	Start with low dosage and gradually increase based on clinical response and tolerability.
Spinal cord injury or disease			Maximum recommended dosage is 80 mg daily [4 mL (20 mg) four times a day].

References

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Clinical Guideline Revision / History Information

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